510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K023885

B. Analyte:
Urinary Glucose
Urinary Occult blood

C. Type of Test:
Urinary Dipstick/Qualitative

D. Applicant:
ANALYTICON BIOTECHNOLOGIES AG

E. Proprietary and Established Names:
COMBI-SCREEN, MODELS 10SL AND 11SL

F. Regulatory Information:

1. Regulation section:
   21 CFR §862.1340 -Urinary glucose (nonquantitative) test system.
   21 CFR §864.6550-Occult blood test.

   Class I exempt:
   21 CFR §862.1785-Urinary urobilinogen (nonquantitative) test system.
   21 CFR §862.1550-Urinary pH (nonquantitative) test system.
   21 CFR §862.1435-Ketones (nonquantitative) test system.
   21 CFR §862.1645-Urinary protein or albumin (nonquantitative) test system
   21 CFR §862.1115-Urinary bilirubin and its conjugates (nonquantitative) test system.
   21 CFR §862.1095-Ascorbic acid test system.
   21 CFR §862.1510-Nitrite (nonquantitative) test system.
   25 CFR §864.9320-Copper sulfate solution for specific gravity determinations.
   21 CFR §864.7675-Leukocyte peroxidase test.
2. Classification:
   Class 2
3. Product Code:
   JIL, JIP
4. Panel:
   Chemistry (75), Hematology (81)

G. Intended Use:

1. Indication(s) for use:
   The urine test strips may be used for rapid determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH, Specific Gravity and Leukocytes in urine for the model 10SL, plus Ascorbic acid in urine for the Model 11SL.

2. Special condition for use statement(s):

3. Special instrument Requirements:
   Not Applicable

H. Device Description:

The COMBI-SCREEN, MODELS 10SL AND 11SL are urine dipsticks for the determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH, Specific Gravity and Leukocytes in urine for the model 10SL, plus Ascorbic acid in urine for the Model 11SL These devices are class I exempt with the exception of urinary glucose and blood.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Medi-Test Combo 11 Macherey-Nagel-Duren
2. Predicate K number(s):
   K991927
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Indication	The urine test strips may be used for determination of Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, Nitrite, pH, Specific Gravity Leukocytes and Ascorbic acid in urine for the model 10SL. urine for the Model 11SL.	Same
Method	Urine Dipstick check against color chart	Same
Timing	60 seconds	Same

J. Standard/Guidance Document Referenced (if applicable):

NCCLS EP 12-P User Protocol for Evaluation of Qualitative Test Performance

K. Test Principle:

The measurement of glucose is based on an enzymatic reaction with glucose oxidase/ peroxidase chromogen. Blood is detected based on the pseudoperoxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide and chromogen producing a green color.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

Qualitative Method-Reproducibility Experiment for Analyte Concentration Near the Cutoff Method Urine samples were prepared at the cutoff concentration and with

concentrations 20% above and 20% below the cutoff concentration. 20 replicate tests were carried out with Combi-Screen.

The experiments were performed according "User Protocol for Evaluation of Qualitative Test Performance", EP12-A, Vol. 22, p. 5-6

Test Strips: Combi-Screen 10 SL three lots: 1483; 1399 and 1458

Glucose Combi-Screen, Analyticon

average value		
20% below	**Cut off: 40 mg/dl**	20% above
3 x pos. = 5,0 %	2 x norm = 3,3 %	60 x pos. = 100%
57 x norm = 95,0%	58 x pos. =96,7%	

result:**cut off: 40 mg/dl**

Blood (lysed and intact) Combi-Screen, Analyticon

concentration	cut off concentration	concentration
20% below	8 Ery/µl	20% above
6,5 Ery/µl		10 Ery/µl
15 x positive = 25,0 %	60 x positive = 100%	60 x positive =100%
45 x negative = 75,0 %		

result: **cut off (lysed Ery) = ca. (approximately) 5-10 Ery/µl**

17 x positive = 28,3 %	4 x negative = 6,7%	60 x positive =100%
43 x negative = 71,7%	56 x positive = 93,3%	

result: **cut off (intact Ery) = ca. (approximately) 5-10 Ery/µl**

b. Linearity/assay reportable range:
Qualitative
Glucose range: negative to 1000 mg/dl
Blood range: negative to 300 Ery/µl

c. Traceability (controls, calibrators, or method):
Not Applicable

d. Detection limit:
Glucose:cut off: 40 mg/dl
Blood: cut off (lysed Ery) = ca. 5-10 Ery/µl
Blood: cut off (intact Ery) = ca. 5-10 Ery/µl

e. Analytical specificity:
Not Applicable

f. Assay cut-off:
Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

The tests were carried out with urine spiked with definite amount of blood or glucose. The evaluation was carried out by comparison of the reaction color of the test strips with the color chart of the label of the relevant test strips meaning:

number: exact value of concentration: color of reaction corresponds to color chart

< the color of reaction is weaker than color chart; but the color can be assigned to color field

> the color of reaction is stronger than color chart; but the color can be assign to color field

- line means: concentration was not tested; there is not color field on the label

In-house Study: visual measurement: Urinary Glucose Testing of Urine Test Strips Combi-Screen on comparison of commercial Urine Test strips Chemstrip 10 (Roche) Glucose spiked urine with glucose concentration

Test Strip	normal	50 mg/dl	100 mg/dl	250 mg/dl	300 mg/dl	500 mg/dl	1000 mg/dl
		observed concentration, (average of 5 measurements)					
Analyticon 10SL 1458	norm	50	100	250	--	500	1000 mg/dl
Analyticon 10SL 1448	norm	50	>100	250	--	500	1000 mg/dl
Analyticon 10SL 1399	norm	50	100	250	--	500	1000 mg/dl
Analyticon 10SL 1316	norm	>50	100	250	--	500	1000 mg/dl
Roche Chemstrip 10 28823742	norm	>50	100	--	300	--	1000 mg/dl

Blood, lysed Ery spiked urine with blood concentration

Test Strips	negative	10 Ery/µl	50 Ery/µl	250 Ery/µl	300 Ery/µl
	observed concentration (average of 5 measurements)				
Analyticon 10 SL 1458	negative	>10	>50	--	300
Analyticon 10 SL 1448	negative	>10	>50	--	300
Analyticon 10 SL 1399	negative	10	50	--	300
Analyticon 10 SL 1316	negative	10	50	--	<300
Roche Chemstrip 10, 28823742	negative	>10	50	250	--

Blood, intact Ery spiked urine with blood concentration

Test Strips	negative	10 Ery/µl	50 Ery/µl	250 Ery/µl	300 Ery/µl
	observed concentration, (average of 5 measurements)				
Analyticon 10 SL 1458	negative	10	>50	--	300
Analyticon 10 SL 1448	negative	<10	>50	--	300
Analyticon 10 SL 1399	negative	<10	<50	--	300
Analyticon 10 SL 1316	negative	5-10	<50	--	<300
Roche Chemstrip 10, 28823742	negative	<10	<50	250	--

b. Matrix comparison:
Not Applicable

3. Clinical studies:

Urine Test Strips Combi-Screen (Analyticon Biotechnologies AG) were tested on comparison to the commercial available test strips Chemstrip 10-Test (Company Roche) by visual measurement at fresh urine samples of patients at three medical centers. The parameter glucose and blood were tested

Reagent areas on the strips were compared with the corresponding color chart on the container 60 seconds after immersion. Colors falling between two color blocks were read as lower of the two values according of the reading procedure of Roche

Urine samples: fresh, uncentrifuged urine, free of detergent, not spiked;

The data analysis of clinical testing were carried out according "User protocol for Evaluation of Qualitative Test Performance", EP 12-P, Section 9 Data Analysis. Data for sensitivity, specificity, predictive value, efficiency of the test were calculated, Table Data Analysis shows the results

Summarized Results of Clinical Testing of the Urine Test Strips Combi-Screen (Analyticon) on comparison to Chemstrip 10 (Roche)

			Günzburg		Lengerich		Potsdam	
Parameter			**Blood**	**Glucose**	**Blood**	**Glucose**	**Blood**	**Glucose**
N total			128	128	102	102	185	182
A true positive			39	4	36	5	68	22
B false positive			2	0	0	0	3	1
C false negative			12	0	11	1	5	0
D true negative			75	124	55	96	109	159
Specificity	100% D/B+D	a)	97,40	100	100	100	97,30	99,40
Sensitivity	100% A/A+C	b)	76.47	100	76,60	83,33	93,20	100
Prevalence	100% A+C/N	c)	39,84	3,13	46,08	5,88	39,46	12,09
PVP	100% A/A+B	d)	95,12	100	100	100	95,77	95,65
PVN	100% D/C+D	e)	86,21	100	83,33	98,97	95,61	100
Efficency	100% A+D/N	f)	89,06	100	89,22	99,02	95,68	99,45

4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:
Literature

M. Conclusion:

The information and data provided by ANALYTICON BIOTECHNOLOGIES AG supports a Substantial Equivalence (SE) determination to other METHOD, ENZYMATIC, GLUCOSE (URINARY, NON-QUANTITATIVE) regulated under 21 CFR §862.1340 - Urinary glucose (nonquantitative) test system., and to other BLOOD, OCCULT, ENZYMATIC METHOD, IN URINE regulated under 21 CFR §864.6550-Occult blood test.